SUPPLEMENTARY QUESTIONS

(Studies involving Medical Ionising Radiation)

26 June 2023

To Be Completed ONLY

when applying to a research ethics committee which has been recognised under S.I. No 29/2023 to grant a single national opinion for a study involving exposure to medical ionising radiation.

Title of Study: ­­­­­­­­­­­­­­­­­­­­­­­­ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Date: \_\_\_\_\_

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# G1 radiation – general

**G1.1 (a) Does this study/trial involve exposure to radiation?** Yes / No

If answer is No, please delete remaining questions in Section G

**G1.1 (b) If yes, please specify:**

**i) Exposure to radioactive materials** Yes / No

**ii) Therapeutic ionising radiation** Yes / No

**iii) Diagnostic ionising radiation** Yes / No

**iv) Other** Yes / No **Details:** Answer

**G1.2 (a) Does this study / trial involve ADDITIONAL radiation exposure other than normally received as part of standard care?** Yes / No

**G1.2 (b) If yes, please elaborate.**

Answer

**G1.3 (a) Please name any sites/institutions at which medical ionising radiation will be administered, state whether the site/institution is a radiation oncology unit, diagnostic imaging facility, clinical laboratory, academic research centre or other, and further confirm that each site/institution which is located in the Republic of Ireland has been licensed by the Environmental Protection Agency. You are required to notify the study to the Radiation Safety Committee / Radiation Safety Adviser at each site/institution (or ‘undertaking’) where medical ionising radiation will be administered.**

|  |  |  |
| --- | --- | --- |
| **Name of site / institution** | **Radiation Oncology Unit / Diagnostic Imaging Facility / Clinical Laboratory / Academic Research Centre / Other** | **Site in the Republic of Ireland Licensed by the Environmental Protection Agency** |
| Answer | Answer | Yes/No/not in Rep of Ire |
| Answer | Answer | Yes/No/not in Rep of Ire |

**G1.3 (b) Please name any sites/institutions at which medical ionising radiation will NOT be administered and the role of this site/institution.**

|  |  |
| --- | --- |
| **Name of site / institution** | **Role** |
| Answer | Answer |
| Answer | Answer |

**G1.3 (c) Please confirm that you are seeking a single national opinion under S.I. No. 29/2023 for those above named sites / institutions which are located in the Republic of Ireland. Please elaborate as necessary.**

Answer

# G2 radiotherapy trials

**G2.1 Does the study/trial involve exposure of patients to radiotherapy?** Yes / No

If answer is No, please delete remaining questions in Subsection G2

**G2.2 (a) Is the planned radiotherapy part of standard treatment or is it experimental in terms of dose / technique / rationale?**

Standard Treatment / Experimental

**G2.2 (b) If experimental, please elaborate.**

Answer

**G2.3 IN RELATION TO THE RADIOTHERAPY PLEASE PROVIDE DETAILS OF THE FOLLOWING:**

**G2.3 (a) Dose Delivery Technique to be used e.g. 3-DCRT (3-dimensional conformal radiation therapy), IMRT (intensity modulated radiation therapy).**

Answer

**G2.3 (b) Imaging/Verification Technique to be used e.g. IGRT (image guided radiation therapy) etc.**

Answer

**G2.3 (c) Radiation treatment schedule:**

 **(i) Total dose:**

Answer

**(ii) Dose per fraction**

Answer

**(iii) Number of fractions per day**

Answer

**G2.3 (d) Expected spectrum of acute and long-term radiation-induced side effects**

Answer

**G2.4 RADIOTHERAPY PLANNING**

**G2.4 (a) Planning Volumes of interest (tumour related volume and organs at risk)**

Answer

**G2.4 (b) Planning Dose volume constraints (DVCs) for organs at risk (OARs).**

Answer

**G2.4 (c) Details of patient positioning/set-up/immobilization, inclusive of pre-treatment preparation e.g. bladder filling protocol, IV contrast etc.**

Answer

**G2.4 (d) Details of radiotherapy plan evaluation parameters (i.e. planning target volume [PTV] coverage)**

Answer

**G2.4 (e) What toxicity scoring criteria are to be used?**

Answer

**G2.5 For experimental radiotherapy, please provide the following information:**

1. **Standard alternatives. Please ensure to detail and contrast the experimental protocol with ‘standard’ therapy.**

Answer

1. **Potential additional risks/toxicities associated with the experimental protocol.**

Answer

**G2.6 (a) Radiotherapy quality assurance at delivery:**

**Please describe the quality assurance programme i.e. PHYSICS quality assurance (beam and dose).**

Answer

**G2.6 (b) Radiotherapy quality assurance at delivery:**

**Please describe the quality assurance programme i.e. CLINICAL quality assurance.**

Answer

**G2.7 Clinical Monitoring/Assessment during radiotherapy and supportive care: please provide a detailed summary of the clinical monitoring of patients included in the study / trial.**

Answer

**G2.8 Criteria for Radiotherapy Adverse Event Reporting**

Answer

# G3 radionuclides

**Please complete the tables below for each radionuclide to be administered**

**G3.1 (a) Will any of the study/trial participants be patients?** Yes / No

|  |
| --- |
| **Details of patients to be studied** |
| **Number (whole study)** | **Age range** | **Sex** | **Clinical condition** | **Total effective or target tissue dose per individual** |
| [TA] | [TA] | [TA] | [TYPE ANSWER=TA] | [TA] |

**G3.1 (b) Will any of the study/trial participants be healthy volunteers?** Yes / No

|  |
| --- |
| **Details of healthy volunteers to be studied** |
| **Number** **(whole study)** | **Age range** | **Sex** | **Total effective dose per individual** |
| [TA] | [TA] | [TA] | [TYPE ANSWER=TA] |

**G3.2 Dose and Risk Assessment**

**G3.2 (a) What is the total research protocol dose from the exposure (if any)?**

Answer

**G3.2 (b) What component of this is the additional** **dose over and above standard practice? What are the risks associated with this dose?**

Answer

**G3.2 (c) Please confirm that a medical physicist has been consulted and is satisfied that the information in sub-section G3.1 and the assessment in sub-section G3.2 provide a reasonable estimate of the ionising radiation exposure planned in this research and the associated risks.** Yes / No

**G3.2 (d) Please provide the name of the medical physicist referred to above and the organisation / institution which employs them:**

|  |  |
| --- | --- |
| **Name of Medical Physicist** | **Name and Address of Employer** |
| Answer | Answer |

# G4 clinical assessment

**G4.1 Will the exposure exceed the exposure that might be received as part of normal care?** Yes / No

**G4.2 Assessment of additional exposure**

**G4.2 (a) Please explain how the planned exposure compares with normal practice and assess whether it is appropriate, using language comprehensible to a lay person. Consideration should be given to the specific objectives of the exposure, the characteristics of participants, the potential diagnostic or therapeutic benefits to the participant, the potential benefits to society, the risk to the participant and the availability of alternative techniques involving less, or no, ionising radiation.**

Answer

**G4.2 (b) If pregnant or breastfeeding mothers are to be studied give reasons and details of special radiation protection measures to be taken.**

Answer

**G4.3 (a) Please confirm that a radiation oncologist / radiologist has been consulted and is satisfied exposure to ionising radiation planned in this research study (as defined in sub-section G2 and/or G3) is reasonable and that the risks are adequately described in the participant information sheet for the study.** Yes / No

**G4.3 (b) Please provide the name of the radiation oncologist / radiologist referred to above and the organisation / institution which employs them:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Position** | **Name and Address of Employer** |
| Answer | Radiation Oncologist / Radiologist  | Answer |